

Feasibility and Outcome of the ROTAPRO System in Treating Severely Calcified Coronary Lesions

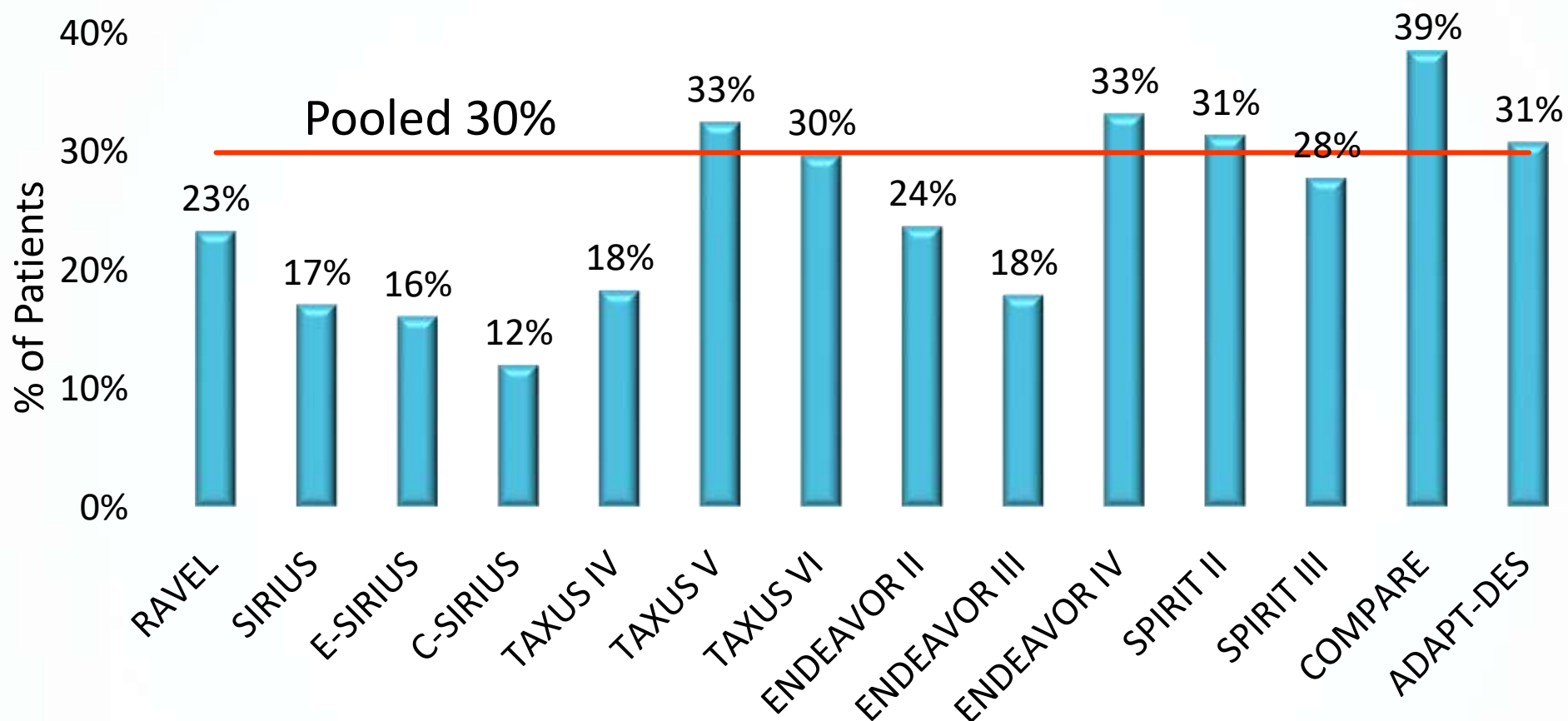
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Disclosures

- **Personal:** **None**
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Abbott, Abiomed, Asahi Intecc, Astra Zeneca, Biotronik, Boston, Cardinal Health, Daiichi Sankyo, Medtronic, Shockwave, SIS, Teleflex, Terumo

Frequency of Angio Core Lab Moderate-Severe Calcification* in 14 DES studies



N	116	531	174	50	660	570	219	590	436	1546	290	997	1799	8582
Year	2002	2003	2003	2004	2004	2005	2004	2003	2004	2005	2005	2005	2007	2008

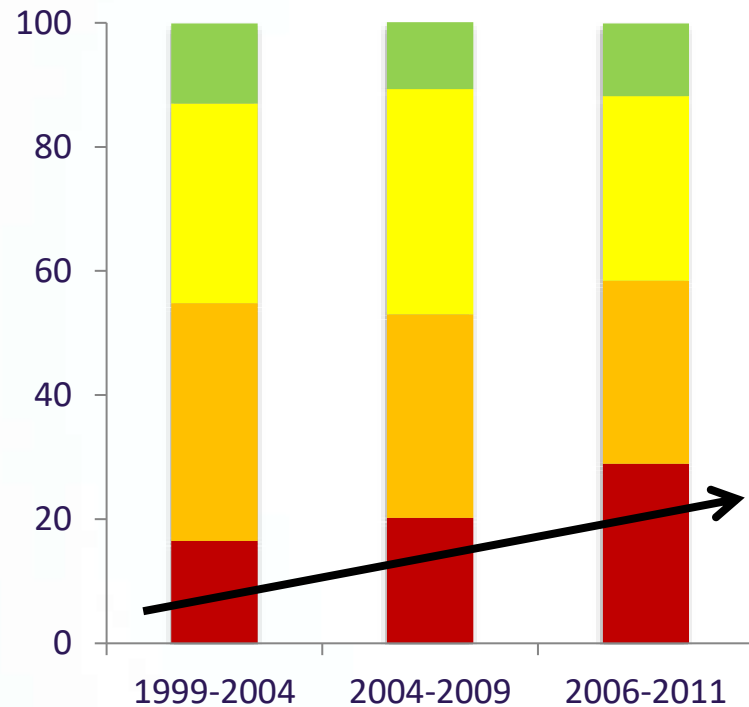
(*despite being an exclusion criterion in most studies)

28 Results from different studies are not directly comparable. Information provided for educational purposes only. Adapted from Kirtane CHIP DC 2017; ADAPT-DES: Généreux, P. et al., *Int. J. Cardiol* ; 2017(231):61-67.



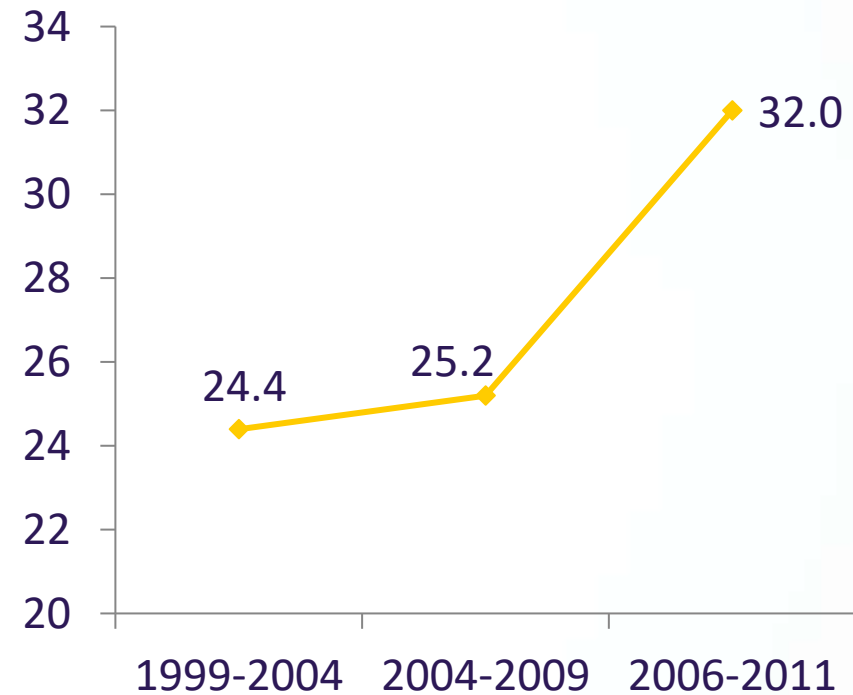
Increasing Complexity and Calcification of PCI Patients

Increasing Prevalence of Type C Lesions



ACC/AHA Lesion Classification

Increasing Prevalence of Calcification



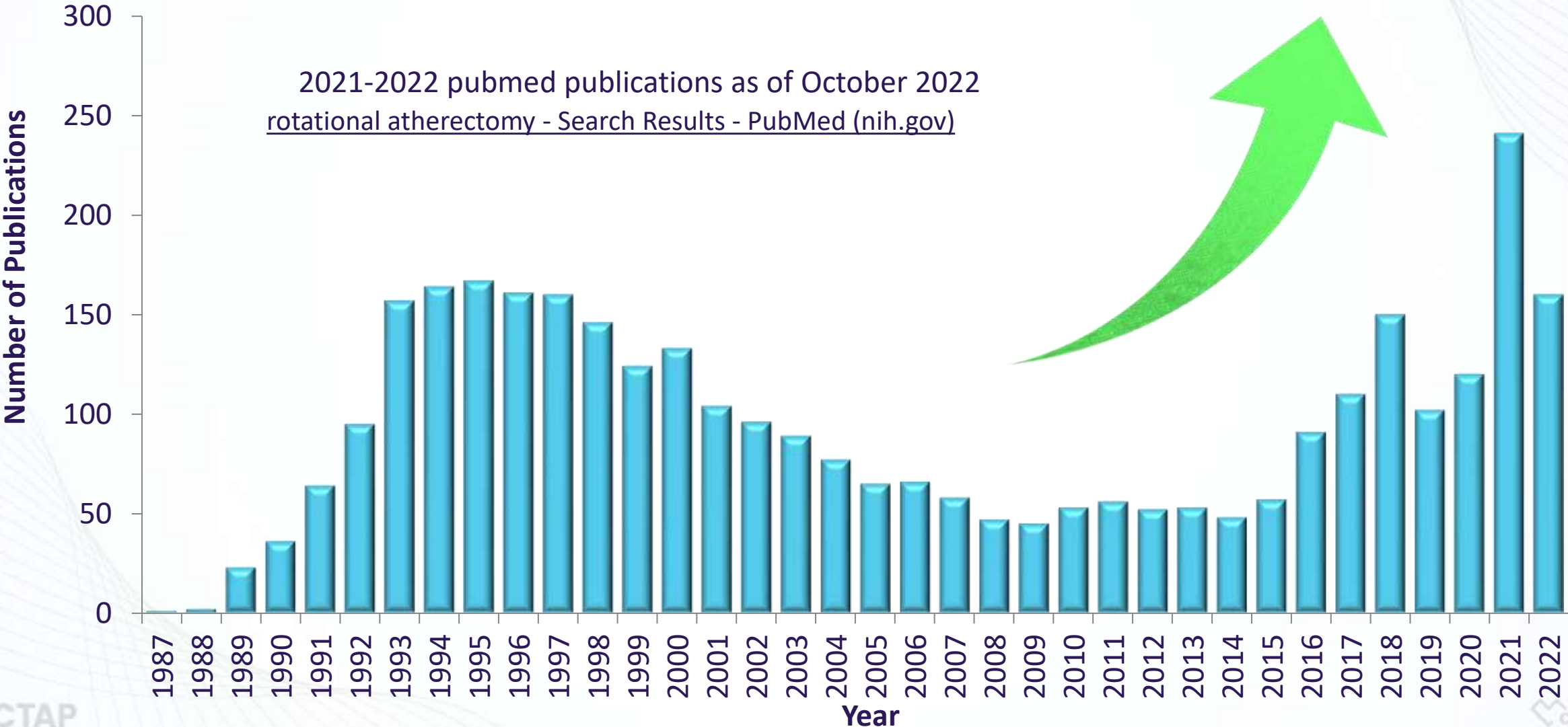
% Of Patients With Calcified Lesions*

*as reported to NHLBI Dynamic Registry.
Bortnick, et. al. Am J Cardiol 2014;113:573-579.

Renewed Interest in Rotational Atherectomy

Number of Publications on Rotational Atherectomy

2021-2022 pubmed publications as of October 2022
[rotational atherectomy - Search Results - PubMed \(nih.gov\)](#)

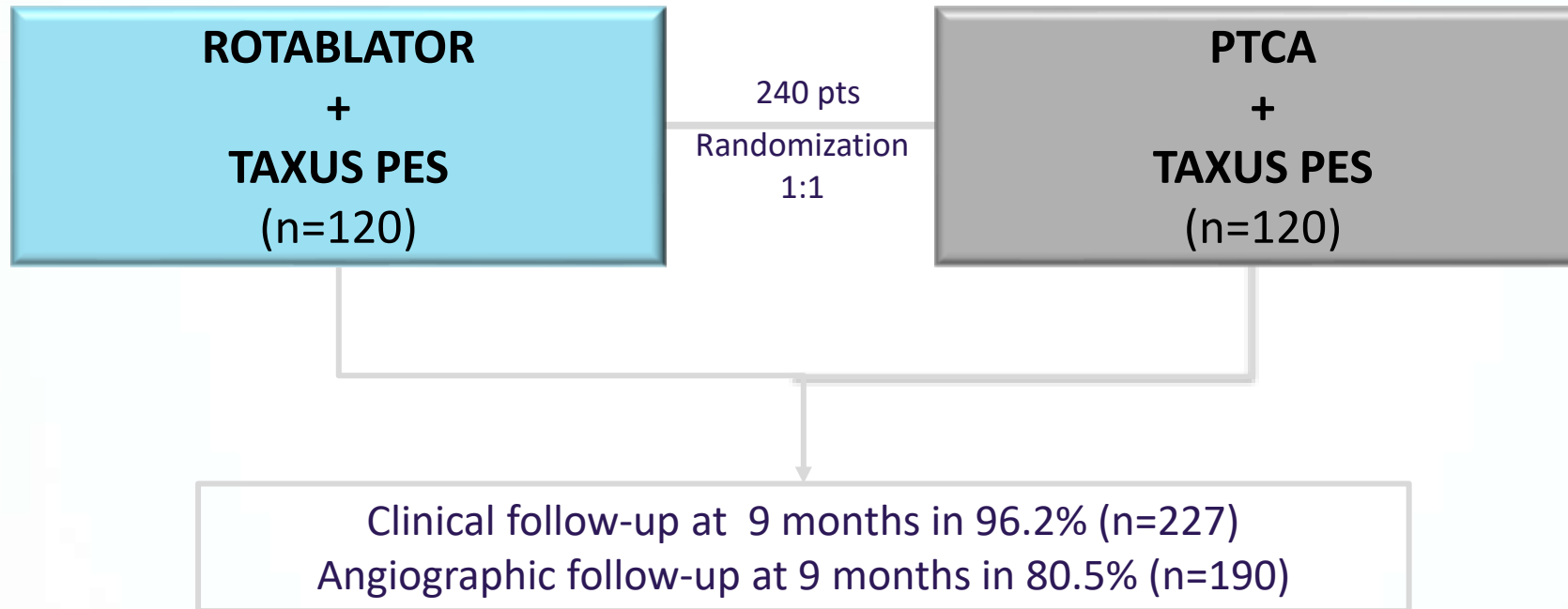


ROTAXUS Trial

Rotablator and 1st generation DES in Complex Coronary Lesions

3 German High-volume centers examining Moderate-to-Severely calcified De Novo lesions

- Key Inclusion: RVD between 2.5-4.0mm, Ostial, bifurcations, and long lesions (≥ 15 mm)
- Key Exclusion: Unprotected LM, Non-native vessels, ISR, CTO, LV EF $<30\%$

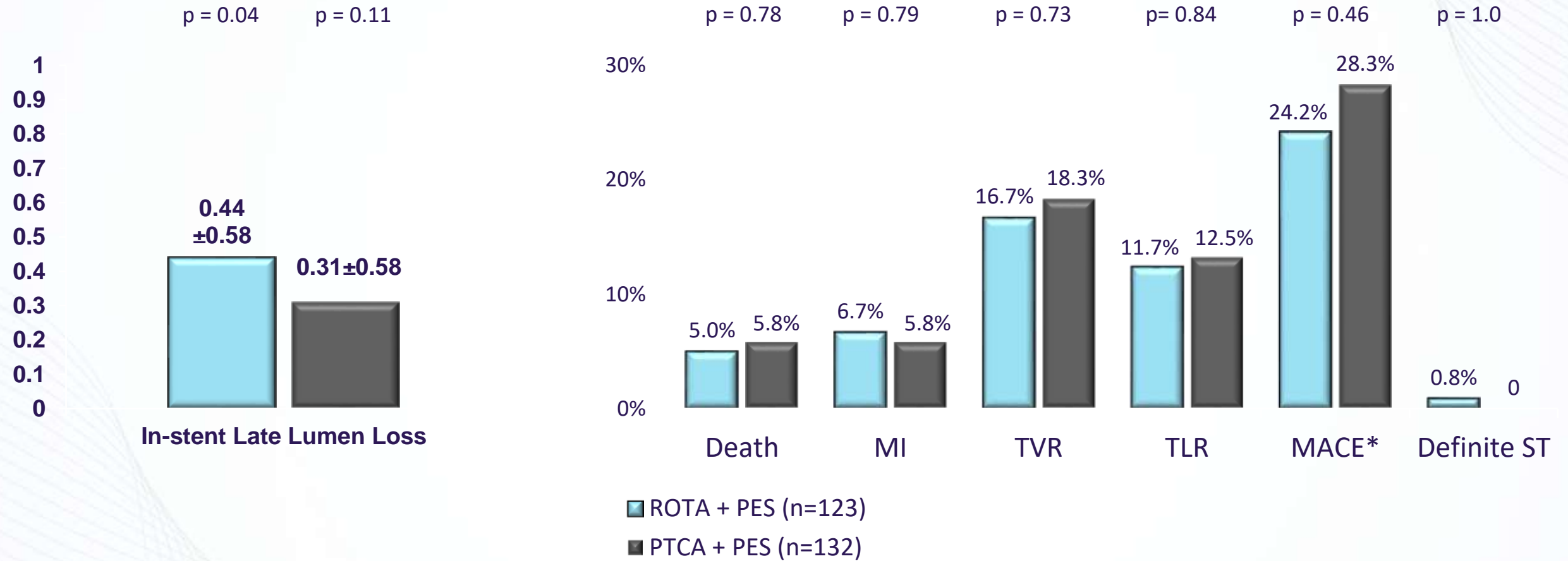


Primary Endpoint: Late-Lumen Loss at 9 months

Secondary Endpoint: Angiographic & Strategy success, binary restenosis, def. ST, MACE at 9 months

ROTAXUS Trial

9-month Primary & Secondary Endpoints

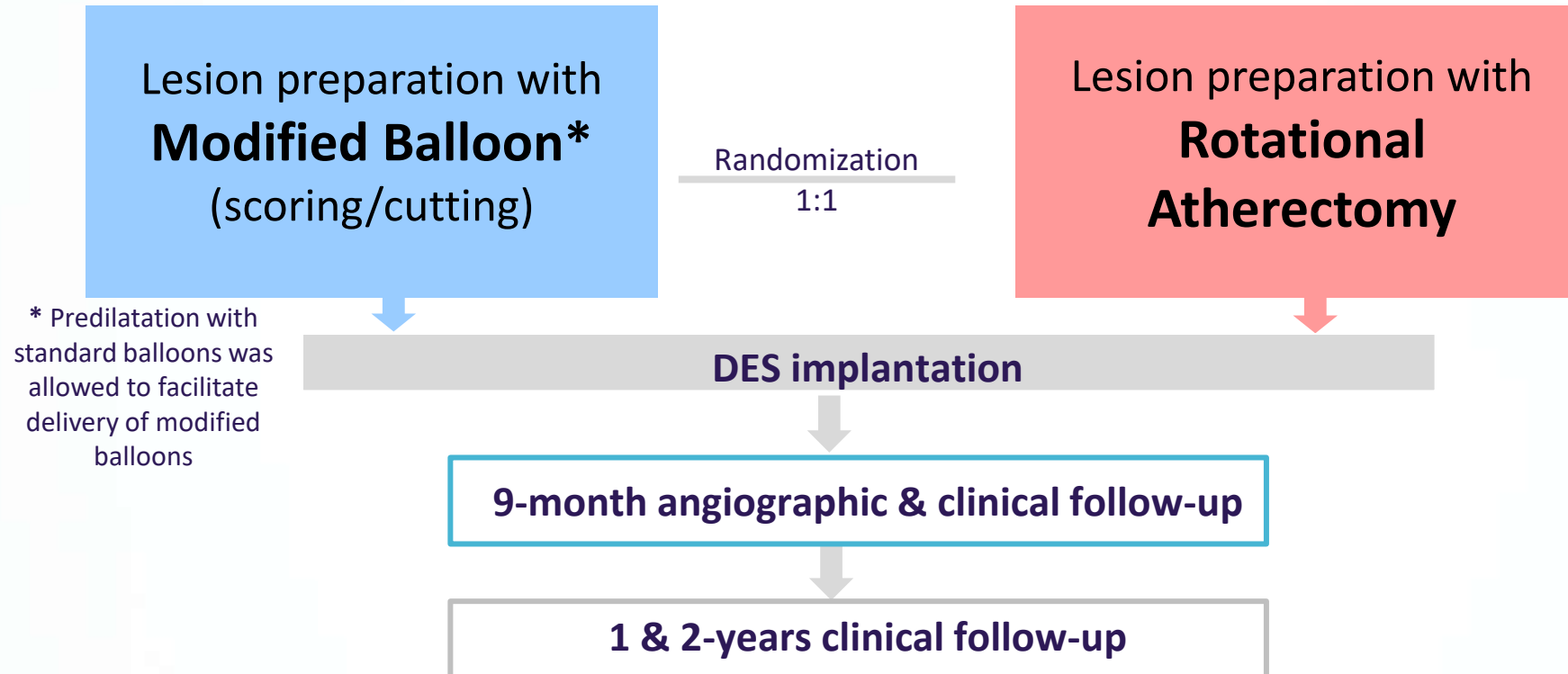


*Defined as death, MI and TVR. RA= rotational atherectomy.
Abdel-Wahab, M. Et al. Circulation: Cardio. Int. 2018 Sep 24.; 11:e007415

PREPARE-CALC Trial

Prospective, 1:1 randomized, German study (2 sites)

PCI in 200 patients with severely calcified lesions

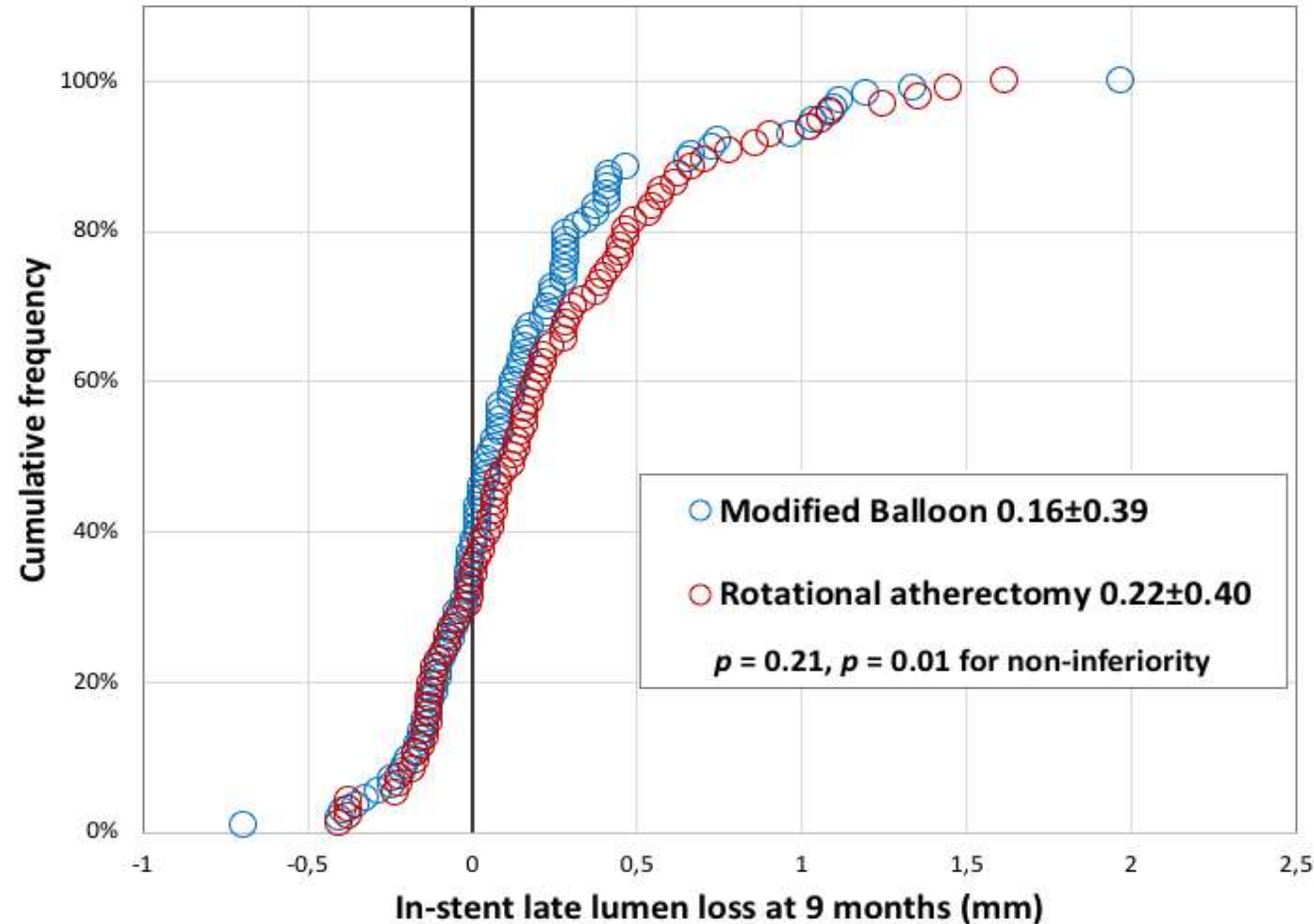


Primary End point:

- **Strategy success (Superiority):** Successful stent delivery and expansion with < 20% in-stent residual stenosis and TIMI 3 flow without crossover or stent failure
- **In-stent late-lumen-loss at 9 months (Non-inferiority)**

PREPARE-CALC Trial

Primary End Point – In-stent Late Lumen Loss at 9 months

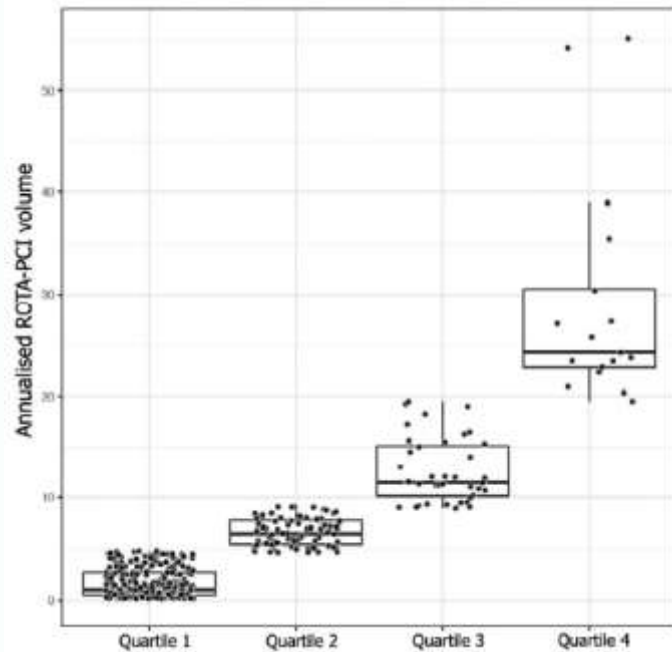


Primary end point for non-inferiority was met with no statistically significant difference for clinical outcomes at 9 months

Is operator volume a significant factor for ROTA-PCI clinical outcomes?

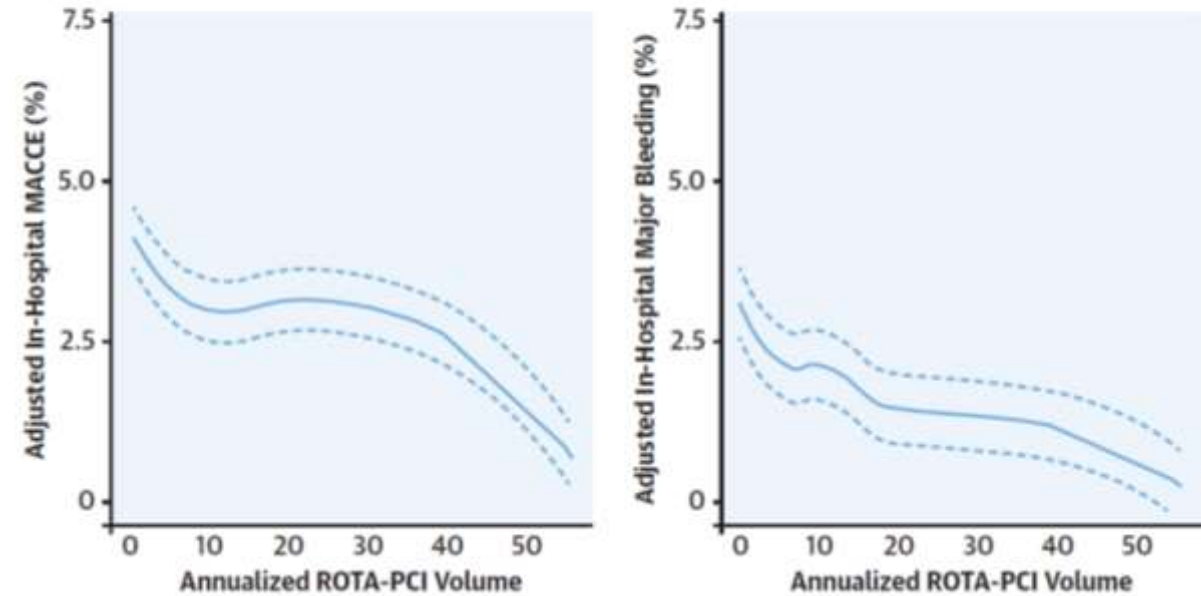
Analysis from BCIS UK National PCI registry

Goal: Study the relationship between operator ROTA-PCI volumes and in-hospital patient outcomes.



#Operators: 303 69 59 17
Median: 1 6.75 11.5 23-33.3

CENTRAL ILLUSTRATION In-Hospital Patient Outcomes Plotted Against Individual Operator Volume Following Percutaneous Coronary Intervention With Rotational Atherectomy in the United Kingdom, 2013 to 2016



Kinnaird, T. et al. J Am Coll Cardiol Interv. 2021; ■(■):■-■.

Higher volume ROTA operators undertake more complex procedures in higher risk patients. Despite this, **significantly less in-hospital outcomes (MACE, major bleeding) as operator volume increased.**

Guideline Updates

2021 ACC/AHA/SCAI Guideline for Coronary Artery Revascularization

Coronary Atherectomy Recommendations:

2011:

Class IIa

1. Rotational atherectomy is reasonable for fibrotic or heavily calcified lesions that might not be crossed by a balloon catheter or adequately dilated before stent implantation.^{514,515} (Level of Evidence: C)

Class III: NO BENEFIT

1. Rotational atherectomy should not be performed routinely for de novo lesions or in-stent restenosis.^{516–519} (Level of Evidence: A)

2021:

COR	LOE	RECOMMENDATIONS
2a	B-R	1. In patients with fibrotic or heavily calcified lesions, plaque modification with rotational atherectomy can be useful to improve procedural success (1-3).
2b	B-NR	2. In patients with fibrotic or heavily calcified lesions, plaque modification with orbital atherectomy, balloon atherotomy, laser angioplasty, or intracoronary lithotripsy may be considered to improve procedural success (4-8).



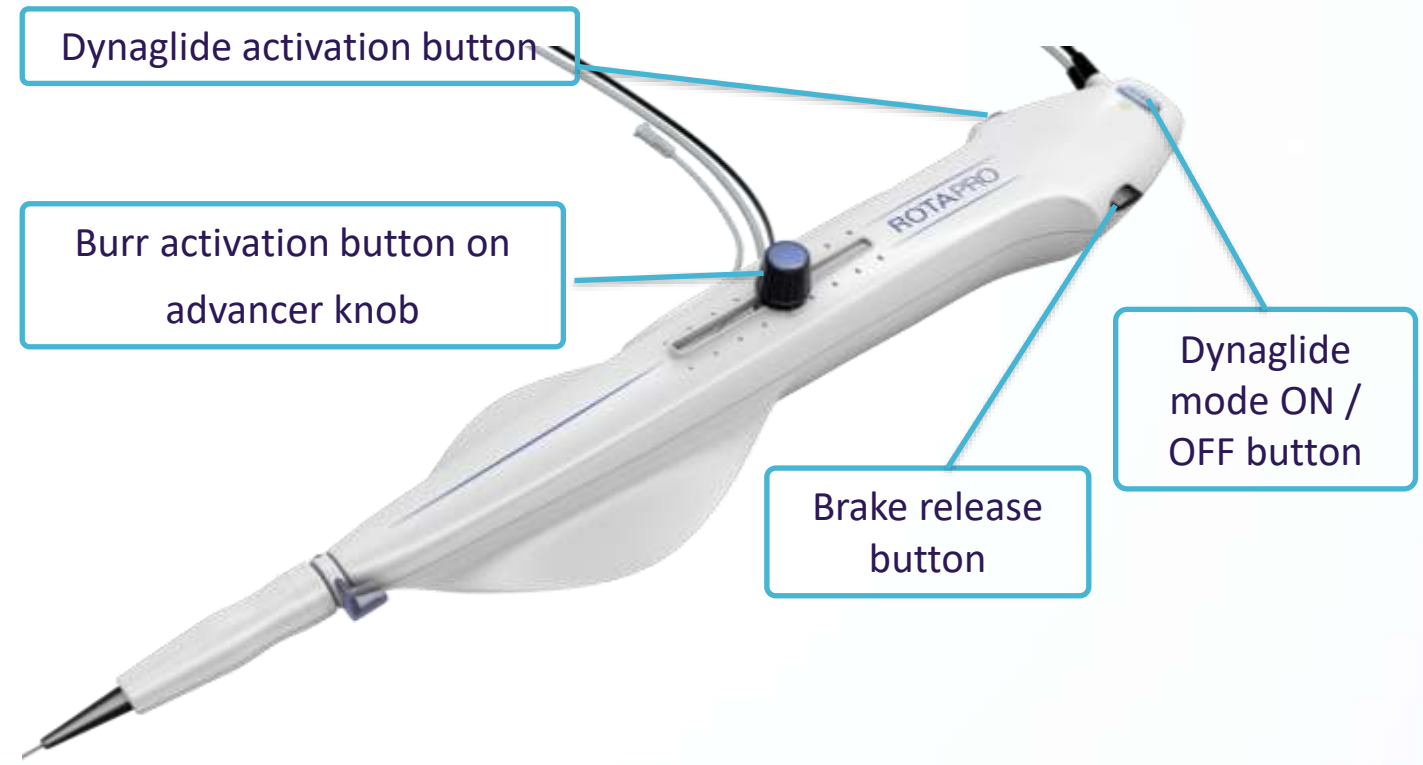
Updated

ROTAPRO™ Rotational Atherectomy System



Design Goals:

- Easier to learn & use (no foot pedal)
- Easier to set up (consolidated cables)
- Allows single operator use



The new ROTAPRO study

The 1st clinical data comparing the new ROTAPRO to legacy ROTABLATOR

Objective: Evaluate safety & feasibility of the new ROTAPRO system for lesion preparation in calcified coronary artery stenosis.

All patient with severely calcified lesions undergoing PCI using RA with **either the new Rotapro system or conventional Rotablator**, followed by DES implantation included in the Bad-Krozingen rotablation registry (1 center, Germany) N= 597

PCI using the new
ROTAPRO system
N= 264

PCI using conventional
Rotablator
N= 351

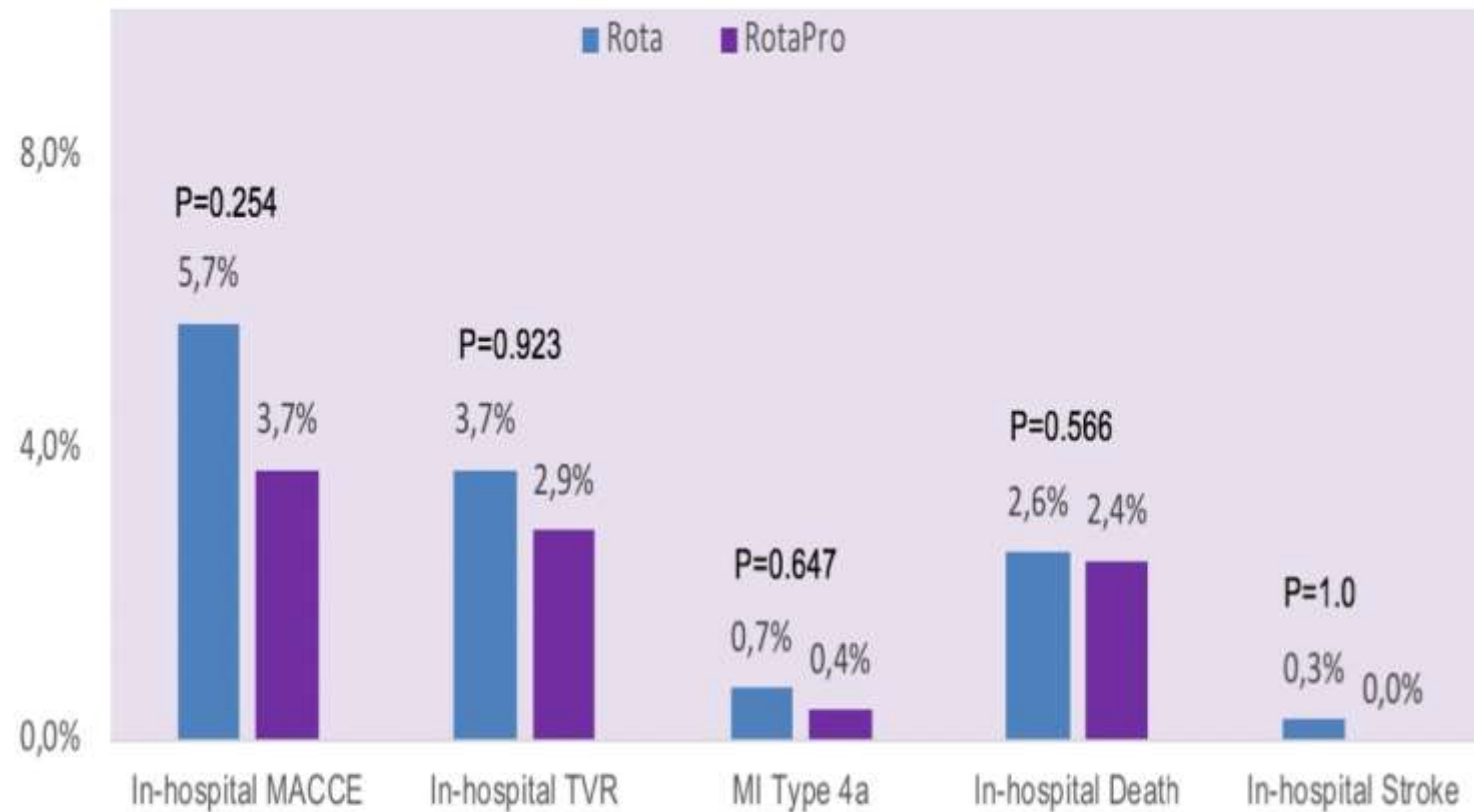
 Primary Endpoint: **In-hospital MACCE** (in-hospital all-cause death, periprocedural MI, recurrent symptoms requiring urgent TVR with PCI or surgery, and stroke).

Secondary Endpoints: Procedural success (technical success without in-hospital MACCE), procedural time, fluoroscopy time, amount of contrast used, major complications.

Mohamed Ayoub, Kambis Mashayekhi et al. Caridol. J. 2021

Results: No differences in in-hospital MACCE

Similar in-hospital MACCE & its individual components



ROTAPRO showed numerically lower in-hospital MACCE, TVR, MI, death or stroke vs. legacy Rota , but without any significant differences in p-values.

Results: Secondary Endpoints & Major Complications

Secondary endpoint (n) %	Total number (n=597)	Rotapro (n=246)	Rota (n=351)	P-value
Procedural endpoints				
Technical success	(589) 98.7%	(244) 99.2%	(345) 98.3%	0.385
Procedural success	(568) 93.8%	(237) 95.5%	(331) 92.6%	0.318
Procedural time (min)	88	82.5	96	0.0003
Fluoroscopy time (min)	34	30	38	0.0001
Contrast volume used (mL)	250	210	290	0.0001
Dose area product (cGy*cm ²)	8011	6129.5	9827	0.0001
Major complications				
Perforation requiring pericardiocentesis	(8) 1.3%	(2) 0.8%	(6) 1.7%	0.348
Vascular access complication	(13) 2.1%	(8) 3.45%	(5) 1.46%	0.206

- ROTAPRO showed significantly **lower procedural & fluoroscopy times** as well as **contrast volume use** compared to conventional rotablation.
- ROTAPRO and Rota both demonstrated high rates of technical & procedural success, with **numerically higher success for ROTAPRO**.

The ROTAPRO Study: Key take-aways

Compared to conventional Rota, ROTAPRO showed:

Similar in-hospital MACCE, including in-hospital all-cause death, peri-procedural MI, TVR and stroke.

Similar procedural success rates and major complication.

Lower procedural time, radiation exposure and contrast use

This study demonstrated **safety and efficacy of using the new ROTAPRO system** for rotational atherectomy.